Transparency in drug regulation: public assessment reports in Europe and Australia

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Openness and transparency are important considerations for medicines regulators, where public health is of paramount concern. As part of their commitment to transparency, the European Medicines Agency (EMA) and Therapeutic Goods Administration (TGA) in Australia publish information relating to their evaluation of medicines via public assessment reports. European Public Assessment Reports (EPARs) and Australian Public Assessment Reports (AusPARs) provide information about the considerations that led the regulator to approve or refuse the application. The reports summarise assessments by each regulator of the information provided on the quality, safety, and efficacy of the medicine under evaluation. Here, we describe the experiences of two established medicines regulators in publishing public assessment reports, and reflect on their future role in communicating medicines information.

Introduction

The TGA and EMA contribute to the protection and promotion of public health as regulatory bodies responsible for evaluating new medicines for human use in Australia and the European Union (EU), respectively. Openness and transparency are important means by which a regulator seeks to provide the public with confidence in its processes [1]. As part of their commitment to transparency, both regulators publish information on their respective websites (EMA: www.ema.europa.eu; TGA: www.tga.gov.au) about their decisions relating to medicines evaluations [2,3]. EMA publishes EPARs and TGA publishes AusPARs. Each public assessment report outlines the outcomes of the evaluation process of the regulator and provides a record of the scientific reasoning on which a decision was made to approve or refuse an application for marketing authorisation. Here, we discuss the rationale and approach for publishing EPARs and AusPARs over time and reflect on their future role in communicating information about medicines.

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Evolution of EPARs and AusPARs

In 1995, the publication of EPARs was a significant pioneering step for a regulatory body and constituted an important milestone in building a regulatory network involving national competent authorities for medicines in 31 European countries. This move was in line with the commitment to public disclosure built into EMA from its inception [4]. In a similar way, the first AusPAR was published in 2009 as part of the commitment of the TGA to the increased transparency strategy of the Australian Government.

EPARs

Following the establishment of the European medicines system in 1995 with an explicit commitment to transparency [5], EPARs were founded on Article 12 of Regulation (EEC) No. 2309/93. This legislation required the agency to make the reasons for granting authorisation available on request. The EMA went beyond this requirement and began publishing EPARs from the very first centrally authorised product in 1995. Although critics did not believe a change to greater transparency was possible because of concerns about safeguarding commercially sensitive information [6], industry gradually accepted the principles of the EPAR. The first EPARs comprise the assessment report and approved product information (PI).

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The assessment report was initially updated with postmarketing changes. However, because of challenges in document layout and readability, this information on postmarketing changes was published separately from 1999 onwards. In 2004, EPAR publication was enacted into Regulation (EC) No. 726/2004, which also introduced the requirement for publication of a summary for the public. These requirements recognised the need to present information in publicly accessible language [7]. This legislation also required publication of assessment reports for those medicines when applications for marketing authorisation were withdrawn or refused. The EPARs of centrally authorised medicines are now updated to incorporate new data throughout the life of the medicine and are available on the EMA website via a dedicated page for each medicine. To the end of 2015, 1179 EPARs for individual human medicines had been published along with 565 EPAR updates for extensions of indications (Fig. 1a).

AusPARs

The first AusPAR was published on 13 November 2009 as part of the implementation by the TGA of an increased transparency

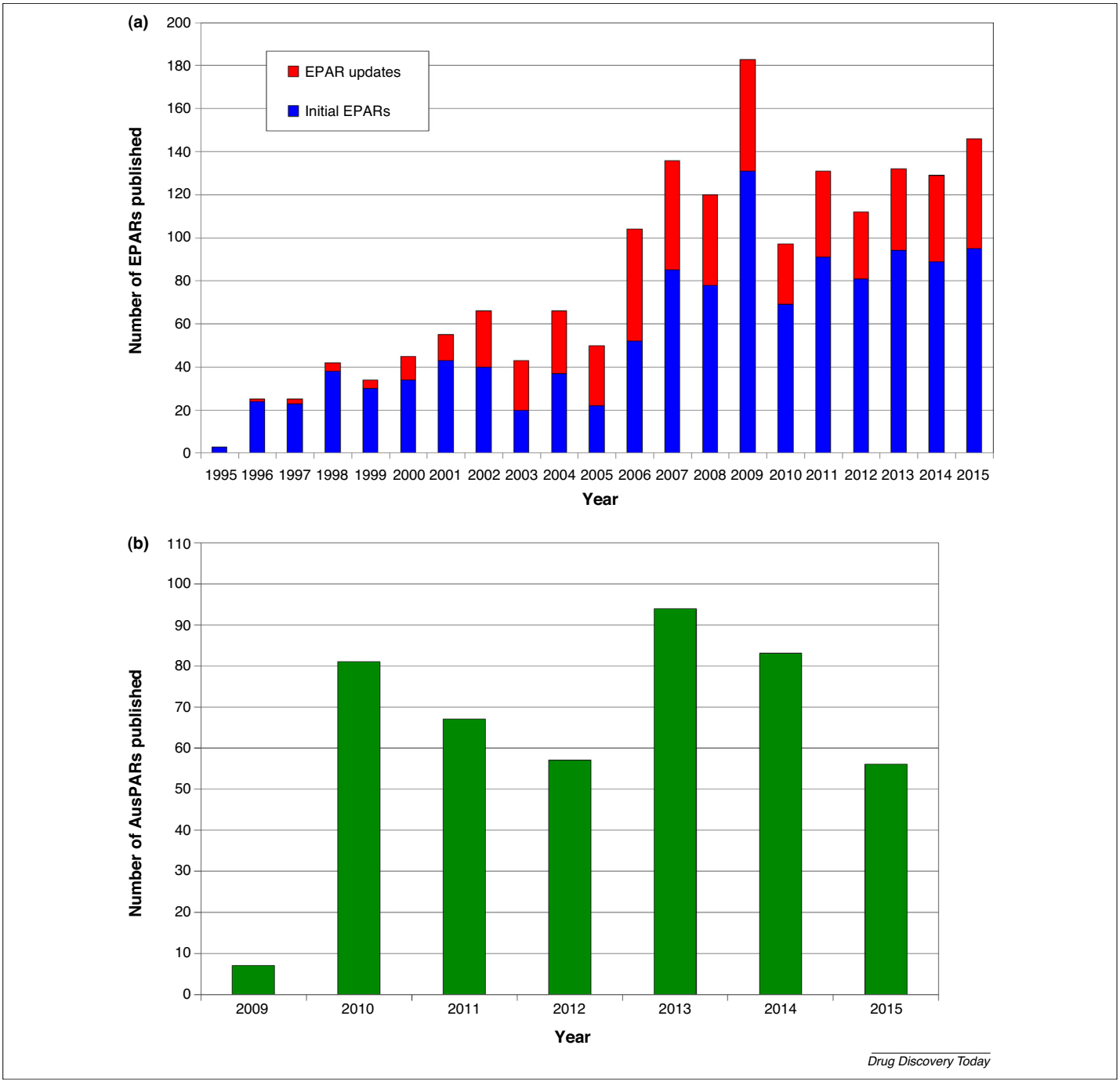

FIG. 1

Number of public assessment reports published annually to 2015. **(a)** European Public Assessment Reports (EPARs) published annually from 1995. 'EPAR updates' indicate extension of indication updates. **(b)** Australian Public Assessment Reports (AusPARs) published annually from 2009.

strategy under the Business Process Reforms for Prescription Medicines. An amendment of legislative provisions followed [Section 61 of the Therapeutic Goods Act 1989 (Cth)].

AusPARs are published for prescription medicine applications considered for entry, or variation of entry, into the Australian Register of Therapeutic Goods (ARTG); these therapeutic goods can then be lawfully supplied in Australia [8]. AusPARs are generally only prepared for applications where TGA has sought advice from its Advisory Committee on Prescription Medicines (ACPM) before a decision and includes all applications relating to new chemical and biological entities and extensions of indications (Table S1 in the supplementary data). Compared with the EPAR, each AusPAR represents the evaluation and decision-making process for a single application, rather than a compilation of decisions for a single medicine. To the end of 2015, a total of 445 AusPARs had been published for 378 individual prescription medicines (Fig. 1b). The majority were for new drug entities (chemical or biological) ($n = 179$; 35.4%) and extensions of indications ($n = 175$; 34.7% of total AusPARs) (Figure S1 in the supplementary data), with most for approved applications ($n = 407$; 91%), 5% ($n = 22$) for withdrawn, and 4% ($n = 16$) for rejected applications.

Content of EPARs and AusPARs

EPARs

The website of the EMA provides, in a single location for each product, a folio of information comprising: (i) the assessment report produced by the original evaluation of the Committee plus further reports for each major change to the marketing authorisation; (ii) the updated PI, comprising the most current version of the Summary of Product Characteristics (SmPC), which is aimed at healthcare professionals, plus the package leaflet for patients and the labelling of the medicine; (iii) a public-friendly and regularly updated summary in a Question and Answer format (EPAR summary); and (iv) a history of procedural changes made to the marketing authorisation (Table S2 in the supplementary data).

The PI and EPAR summary are translated into 25 European languages to serve the multilingual environment of the EU. The PI provides the necessary information for both healthcare professionals and patients on how to use the medicine safely and effectively. Assessment reports provide detailed medical and scientific information; these are now often over 100 pages and are published in English only.

AusPARs

Each AusPAR webpage contains three documents: (i) the AusPAR itself; (ii) the Extract from the Clinical Evaluation Report (CER), published as a separate attachment; and (iii) for approved applications, the PI approved with the application, also published as an attachment.

AusPARs incorporate assessment summaries of the quality, safety, and efficacy of the medicine using reports prepared as part of the evaluation and decision-making process of the TGA. The Extract from the CER is the clinical evaluator's report presented in full other than deletions of commercially confidential clinical information as justified by the sponsor. The publication of the Extract from the CERs began in July 2013; before this, clinical information was included in the AusPAR itself. This change was implemented to make the AusPAR more concise and focus its content on the decision process. Currently, the average AusPAR length is 70–90 pages; readers seeking more detailed clinical data are able to access the CER Extract document. AusPARs are published in English only.

Content and structure of assessment reports

Assessment reports have the same basic format (Table 1), and the structure of AusPARs was modelled on that of EPARs. Their structure and content mirror the legal requirements contained in the standards and protocols for the development of new medicines [9], and follow the internationally agreed format [10], in which applicants are required to submit these data when applying for a marketing authorisation.

In each public assessment report, the main findings of tests and studies are presented after describing their methodologies. Results are discussed in the light of compliance with guidelines on the development of medicines [11] and with principles of good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP), and good pharmacovigilance practice (GVP). Clinical data supporting the marketing authorisation are presented and discussed in depth. The main studies are described in accordance with the general principles of the CONsolidated Standards of Reporting Trials (CONSORT) 2010 statement on the transparent reporting of clinical trials [12]. Clinical safety information is concluded with a summary of important identified or potential risks, missing information, proposed pharmacovigilance activities, and related risk minimisation measures. Throughout the assessment report, attention is paid to ensure that information in the PI optimises the benefits and manages the risks of each medicine.

The assessment report concludes with the recommendation for marketing authorisation (or not) after a transparent, objective, and explicit description of the benefit–risk balance. For example, the benefit–risk balance is described after presenting the beneficial effects, the unfavourable effects, and their related uncertainties. Assessment reports also include any views or recommendations following consultation with a scientific advisory group or ad hoc expert group. If a sponsor appeals a decision, the re-examination assessment is also incorporated into the report. In the EU, the final report is adopted by the Committee for Medicinal Products for Human Use (CHMP) before redaction for publication. When an opinion on an authorisation has not been granted consensually, the divergent positions expressed by Committee members are appended to the assessment report. This additional information provides in-depth transparency on the entire decision-making process.

Commercially confidential information is redacted where the sponsor can justify deletion. Redaction is in accordance with principles for the deletion of commercially confidential information and the regulators' policies on transparency [13,14]. Nonclinical and clinical information, together with the accompanying evaluation, are generally not considered confidential. By contrast, detailed manufacturing information is usually regarded as commercially sensitive. Figures S2 and S3 in the supplementary data show how TGA applies these principles and classifies commercially confidential information. The final decision concerning AusPAR and EPAR content rests with TGA and EMA, respectively.

TABLE 1

Content of assessment reports[a]

Part	Components
1. Background information	a. Basic information about the product, extracted from the submission
2. Scientific discussion	a. Introduction i. Problem statement about the product and its development in relation to the disease for which an indication is claimed b. Quality aspects i. Active substance ii. Finished medicinal product iii. Summary of the chemical, pharmaceutical, and biological aspects c. Nonclinical aspects i. Pharmacology ii. Pharmacokinetics iii. Toxicology iv. Ecotoxicity/environmental risk assessment v. Summary of the nonclinical aspects d. Clinical aspects i. Pharmacokinetics ii. Pharmacodynamics iii. Summary of clinical pharmacology e. Clinical efficacy i. Dose response studies ii. Main studies (Phase III; therapeutic confirmatory trials) iii. Summary of clinical efficacy f. Clinical safety i. Patient exposure, adverse events (AEs), serious adverse events (SAEs), laboratory findings ii. Safety in special populations iii. Summary of clinical safety g. Pharmacovigilance system h. Risk management plan (RMP)
3. Benefit-risk balance	a. Assessment of benefits b. Assessment of risks c. Assessment of benefit–risk balance
4. Recommendations and conclusion	a. Overview of the salient issues identified during the evaluation b. Decision, including rationale

[a] AusPARs also include the sponsor's response to the salient issues included in the Overview section (4a). Similarly, the applicant's response to CHMP questions are also included in the assessment report for an EPAR, and are integrated in the most relevant part described above.

Audiences for EPARs and AusPARs

Publication of EPARs and AusPARs on the regulators' websites provides access for a broad audience. Here, we discuss the major categories of stakeholders.

Pharmaceutical industry

The pharmaceutical industry represents an important audience of medicines regulatory websites. A 2011 EMA web survey indicated that 65% of responders were from industry; similarly, a 2016 TGA web survey showed 67% of responders were from industry. A 2008 EMA web survey showed that 75% of web users rated the EPAR as good or very good. In 2011, an independent Australian survey of 20 companies found that 75% of respondents rated their satisfaction with AusPARs as 'medium', with 15% saying it was 'high' [15]. The same survey reported that industry believes that AusPARs are used as a source of competitive information. Greater transparency might also assist industry by making the regulatory process clearer and more predictable.

Other health authorities

In the EU, Health Technology Assessment (HTA) bodies have expressed interest in EPARs. These bodies assess the relative effectiveness of medicines to make judgements concerning their usefulness to the healthcare system in their jurisdiction or to support decision-making on price and reimbursement. In 2008, EMA and the European network for HTA (EUnetHTA) initiated a partnership with the aim that EPARs will further contribute to assessments of relative effectiveness. As a result, the template of the European assessment report was revised in 2010 to include a standardised tabular overview of the main efficacy data from the pivotal studies, along with additional guidance for discussing critical aspects of study design, such as endpoints and comparators, or considerations on subgroup analysis [16].

The publication of EPARs also supports the work of the EMA with health authorities outside the EU. This includes the provision of certificates to confirm the marketing authorisation status of medicines submitted through the centralised procedure. In cooperation with the World Health Organization (WHO), the EMA provides scientific opinions on medicinal products intended exclusively for markets outside the EU (Article 58 of Regulation 726/2004/EC); EPARs are also produced for these scientific opinions.

Healthcare professionals and patients

From the beginning, EMA has interacted with healthcare professionals and patients, with their involvement growing over time

[17]. In 2009, the EMA group working with healthcare professionals [18] stressed that the SmPC is the reference document on the safe and effective use of a medicine, with the EPAR substantiating this information by describing the benefit–risk balance of each medicine and informing about risk management activities. EMA regularly consults patient representatives in the preparation of EPAR summaries and package leaflets.

TGA provides access to the Consumer Medicines Information (CMI) document for each medicine on its website. This document is written by the pharmaceutical company and contains information on the safe and effective use of a medicine in lay terminology.

AusPARs are already shared with editors of drug bulletins through National Prescribing Service (NPS) MedicineWise, a non-profit organisation providing medicines information through *Australian Prescriber* [19]. This facilitates the timely dissemination of important medicines information to the public. Drug bulletins have also communicated interest in EPARs. Today, public assessment reports are shared through the social media platform Twitter (@TGAgovau; @EMA_News) to further expedite the sharing of medicine information with patients.

Web traffic

TGA web trends indicate a steady annual rise in visits to AusPAR pages: from 0.74% in 2010 to 11.47% in 2014, a 15-fold increase in 5 years (Fig. 2). EMA monitoring shows that EPAR webpages are the most viewed pages on the EMA website. In November 2014, visits to EPAR pages represented 8.90% of total EMA website traffic (Table S3A in the supplementary data); this had increased to 10.36% in September 2015 (Table S3B in the supplementary data).

The AusPAR remains the most viewed document online, outperforming Extract CER and PI documents overall (Fig. 3). Extract CER documents had a relatively low proportion of views following their separation from the AusPAR document in July 2013, although the numbers have slowly increased over time (Figure S4 in the supplementary data). The average number of visits per individual most AusPAR online users are from Australia, there is also substantial international interest, particularly from the USA and China (Figure S6 in the supplementary data).

Even though most published AusPARs have been for antineoplastic and immunomodulating agents ($n = 110$; 23%) (Figure S7 in the supplementary data), the most viewed AusPARs are for nervous system drugs (28.0% of the top 25 AusPARs viewed; Figure S8 in the supplementary data). Medicines for cardiovascular diseases, which were eight of the top ten most prescribed drugs in Australia for 2012–2013 [20], ranked second for views (17.6%). As far as application types are concerned, AusPARs for new chemical and biological entities were the most viewed (38.4% of the top 25 AusPARs; Figure S9 in the supplementary data). There was no distinct difference in web traffic according to decision outcome (data not shown). Table S4 in the supplementary data shows the

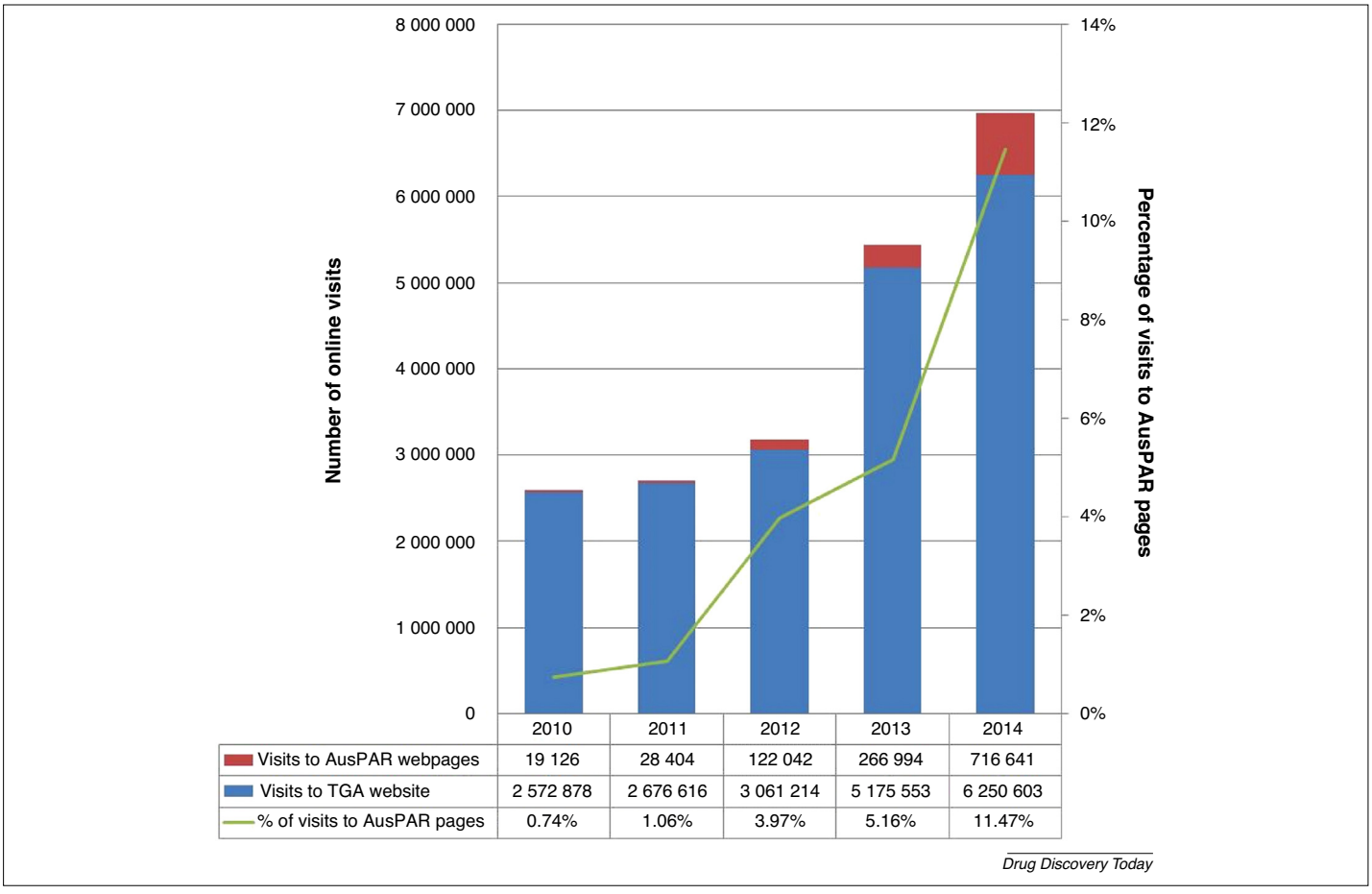

FIG. 2

Overall Australian Public Assessment Reports (AusPARs) web traffic 2010–2014.

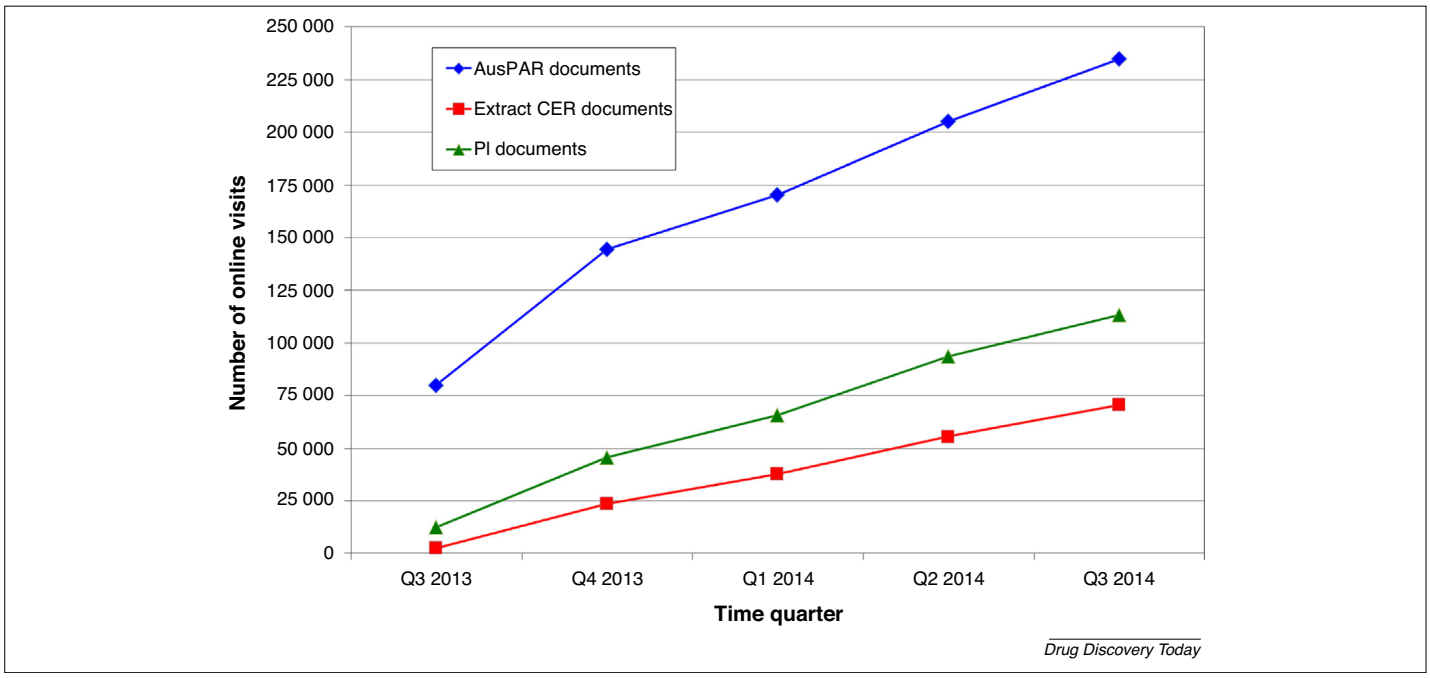

FIG. 3

Visits to individual document types on Australian Public Assessment Reports (AusPARs) web pages per quarter (July 2013 to December 2014).

most viewed individual AusPAR documents during the period 2010–2014.

The web traffic of individual medicines documents over time showed that most AusPARs produce an initial spike in web traffic soon after publication (Figure S10 in the supplementary data). A listing of the medicine on the Pharmaceutical Benefits Scheme (PBS), by which the Australian Government provides subsidised prescription drugs to all Australian residents [21], could also produce a second spike in web traffic. For certain documents, web traffic was cyclical, such as spikes for influenza vaccines during the influenza season (Figure S10 in the supplementary data).

Discussion of shared experience

Comparing TGA and EMA practices on public assessment reports, we see a high degree of similarity in terms of content. Even though the precise scopes of publication differ, both regulators publish comprehensive information on their respective assessments. Published information presents the basis for the decision of each authority, together with more detailed supportive data (e.g., clinical trials or PI documents). More significant differences are observed in the process and publication formats. Whereas TGA publishes an AusPAR for each assessment, EMA brings together all medicines information in a single location, the EPAR webpage. EMA publishes the report as adopted by its Committee at the time of opinion, which is later complemented with a short public summary. By contrast, TGA prepares an AusPAR after a decision has been made and attaches the Extract CER document. Although a detailed comparison with other authorities is beyond the scope of this paper, many regulators now publish extensive information on the assessment of medicines; for example, in the USA through the Drugs@FDA database (www.accessdata.fda.gov/scripts/cder/drugsatfda) or in Canada with the publication of 'Summary Basis of Decision' (SBDs; www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/index-eng.php). Overall, it is clear that regulators share the same objectives of transparency and the provision of up-to-date information even though there are differences in the format and structure of published information.

Web statistics indicate a high interest in EPARs and AusPARs. EPAR webpages are the most viewed on the EMA website, while the AusPAR readership has consistently grown over time. Monitoring of web statistics provides an insight into audiences' preferences. For example, although TGA initially believed that readers would increasingly start accessing AusPARs at the expense of Extract CERs, the data have shown the opposite, with Extract CER readership gradually increasing over time. This underscores the importance of maintaining a high level of transparency on clinical data in the assessment report alongside the publication of clinical trials data in separate databases by EMA. In the interests of public health, the TGA and EMA are mindful of timely publication of AusPARs and EPARs, respectively.

The degree of openness represented by the publication of public assessment reports was a major pioneering step for the two regulatory bodies. Increasing publication has served as an 'internal audit', raising the bar for the quality and readability of assessment reports over time. Publication has evolved with the needs of the various audiences, from the addition of a short public summary (EPARs) to the separate publication of the Extract CER (AusPARs). Publication of EPARs and AusPARs require resources (including for quality assurance) but facilitates answering requests for information or access to documents (Figure S11 in the supplementary data). Today, about a quarter of requests for information to EMA from healthcare professionals and patients resulted in reference to EPARs, while about one-third of requests to TGA were directed to AusPARs.

EMA and TGA regularly consult one another and share information related to establishing the safety, quality, and efficacy of new medicines. Ongoing communication between regulators will allow for the sharing of ideas and continued evolution of public assessment reports.

Looking forward

Transparency is a fundamental value in developed societies and is regarded globally as a key feature of a sound national regulatory system. Patients and healthcare professionals have a right to know about the scientific basis for the approval and use of their medicines [1]. Publication of assessment reports by regulators ensures transparency in communicating the scientific rationale about the regulatory decision-making process. Beyond the conclusion of the regulator, public assessment reports describe the data submitted to support the request for marketing authorisation and the discussions during assessment; for example, regarding data limitations, uncertainties, or different views of parties involved in the evaluation. Both EPARs and AusPARs provide up-to-date information on medicines in line with the latest recommendations for safe and effective use as presented in the PI. The value of providing accurate, evidence-based information on medicines is enhanced in the context of a large amount of unreliable or at least nonvalidated information available, particularly on the internet [22].

The full impact and readership of EPARs and AusPARs by target audiences is not currently known. However, transparency in the assessment of applications assists industry in the requirements and procedures of the regulatory process. Public assessment reports also provide information that might be relevant to support the relative effectiveness of a medicine compared with alternative therapy, or information on available experience in specific subpopulations. It might also make it easier for stakeholders to review data from previous trials or compare data from different trials as part of their research [23]. Public assessment reports can help readers understand the rationale for divergent outcomes by regional competent authorities.

Rapid scientific progress over the past 10 years has led to an increase in both the quantity and complexity of the information that medicine regulators communicate. Along with stakeholders' desire for greater transparency, the quantity of information contained in each public assessment report and the number of associated documents have increased over time. A significant challenge for EMA and TGA is to address these diverse stakeholder requirements. Both EPARs and AusPARs represent an important tool for communicating valuable medicines information; however, given that multiple stakeholders have diverse needs, it is acknowledged that one tool might not suit all [24]. For example, healthcare professionals are likely to have needs and expectations that need to be supported by a variety of information: either concise, targeted information addressing specific points in clinical practice, or detailed information to learn about available evidence and possibly stimulate further research. Patients are also becoming more engaged and knowledgeable about treatment decisions, which gives rise to a greater demand for reliable information.

Continuing to gather more extensive feedback on the value of published information is an important objective for both regulators. There is obvious value in involving stakeholders to obtain their perspectives and tailor communication tools appropriately. At the time of writing this paper, TGA were undertaking a comprehensive survey to obtain such feedback from AusPAR readers. Preliminary findings show that 79% of respondents feel that AusPAR documents provide transparency in the TGA's decision-making process either very well (39%) or well (40%), while 84% feel that AusPAR documents are either very useful (36%) or useful (48%) for their needs. Similarly, EMA continues to assess how to best communicate high-quality information throughout of the lifecycle of a medicine. Another key project in the EU potentially impacting the future of EPARs will be the development of the EU Medicines Web Portal, which aims to create a multi-lingual website giving access to information on authorised medicines, irrespective of the EU licensing route [25].

EMA is committed to continuously extending its approach to transparency. A key goal in this process is the future publication of clinical trials data for medicines [26]. This higher degree of transparency will benefit public health by allowing medicine developers to learn from past successes and failures or enable the wider scientific community to make use of detailed clinical data to develop new knowledge. It might also allow third parties to verify original analysis and conclusions, to conduct further analyses, and to examine the positions of the regulator and challenge them where appropriate. TGA does not currently plan to publish clinical trials information.

At a time when even more detailed scientific information is becoming available, continued dialogue between medicines regulators and their audiences is essential. Regulators' efforts in terms of publication of information on medicines should be driven towards accessibility and usability by stakeholders. This could be the opportunity to address the challenge of providing the most relevant information on medicines at the levels of detail appropriate to the needs of stakeholders.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at http://dx.doi.org/10.1016/j.drudis.2016.06.025.

References

1 Bonini, S. *et al.* (2014) Transparency and the European Medicines Agency: sharing of clinical trial data. *N. Engl. J. Med.* 371, 2452–2455

2 Rawal, B. and Deane, B.R. (2014) Clinical trial transparency: an assessment of the disclosure of results of company-sponsored trials associated with new medicines approved recently in Europe. *Curr. Med. Res. Opin.* 30, 395–405

3 McGee, R.G. *et al.* (2012) Medical device regulation in Australia: safe and effective? *Med. J. Aust.* 196, 256–260

4 Anon. (1995) European medicines in the 21st century. *Lancet* 345, 1–2

5 Sauer, F. (1995) Agence européenne pour l'évaluation des médicaments. *Actual. Dossier Santé Publ.* 11, 10–12

6 Lekkerkerker, F. and Gonal, F. (2004) *European Medicines Agency, Celebrating Ten Years: Portrait of the European Medicines Agency*. EMA
7 Anon. (2006) *European Medicines Agency, Reflection Paper: EPAR Summary for the Public*. EMA
8 Hammett, R. and Hunt, L. (2009) The Australian medicines regulatory system: a risk-based approach to regulation. *Ther. Innov. Regul. Sci.* 43, 17–20
9 Anon. (2001) *Directive of 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use*. European Parliament and the Council of the European Union
10 Anon. (2004) *European Medicines Agency, ICH Topic M 4 Common Technical Document for the Registration of Pharmaceuticals for Human Use – Organisation CTD*. EMA
11 Anon. (2009) *European Medicines Agency, Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework*. EMA
12 Schulz, K.F. *et al.* (2010) CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *PLoS Med.* 7, e1000251
13 Anon. (2007) *Principles to be Applied for the Deletion of Commercially Confidential Information for the Disclosure of EMEA Documents*. EMA
14 Anon. (2014) *TGA Approach to Disclosure of Commercially Confidential Information (CCI)*. TGA
15 Mullen, L. (2011) *AusPAR Concern at High Levels. Pharma in Focus*.
16 Berntgen, M. *et al.* (2014) Improving the contribution of regulatory assessment reports to health technology assessments—a collaboration between the European Medicines Agency and the European network for Health Technology Assessment. *Value Health* 17, 634–641
17 Anon. (2011) *Framework for Interaction between the European Medicines Agency and Healthcare Professionals*. EMA
18 EMA (2009) *EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG): Final Recommendations and Proposals for Action*. EMA
19 Dowden, J.S. (2006) End of contract for Drug and Therapeutics Bulletin: Australian Prescriber was resurrected. *BMJ* 332, 1273
20 Anon. (2013) Top 10 drugs. *Aust. Prescrib.* 36, 211
21 Pearson, S.A. *et al.* (2015) Studies using Australia's Pharmaceutical Benefits Scheme data for pharmacoepidemiological research: a systematic review of the published literature (1987–2013). *Pharmacoepidemiol. Drug Saf.* 24, 447–455
22 Pohjanoksa-Mantyla, M. *et al.* (2011) Is the Internet replacing health professionals? A population survey on sources of medicines information among people with mental disorders. *Soc. Psychiatry Psychiatr. Epidemiol.* 46, 373–379
23 Hunter, P. (2015) More transparency for clinical trial data: the decision by the European Medicines Agency to make clinical trial reports publicly available could provide a boon for biomedical research. *EMBO Rep.* 16, 21–23
24 European Medicines Agency (2009) *Information on Benefit–Risk of Medicines: Patients', Consumers' and Healthcare Professionals' Expectations*. EMA
25 European Medicines Agency (2015) *EU Telematics Strategy and Implementation Roadmap 2015–2017*. EMA
26 European Medicines Agency (2014) *European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use*. EMA